

REMS Patents Should Not be Listed in Orange Book

Submission for Docket No. FDA-2020-N-1127: "Listing of Patent Information in the Orange Book"

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I. REMS Patents Not Similar to Categories Listable in Orange Book

- A. REMS patents are not similar to the categories listable in the Orange Book
 - 1. Orange Book listings limited to any patent that "claims the drug" or "claims a method of using such drug." 21 U.S.C. § 355(b)(1).
 - a. Listable patents: "drug substance (active ingredient) patents, drug product (formulation and composition) patents, and method-of-use patents." 21 C.F.R. § 314.53(b)(1).
 - 2. Patent holders cannot list in Orange Book "[p]rocess patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediaries." 21 C.F.R. § 314.53(b)(1).
 - 3. REMS patents do not claim a method of *using* a drug product for therapeutic reasons; they claim a method of controlling a drug's *distribution* through the supply chain

II. Listing of REMS Patents in Orange Book Harms Competition

- A. Listing of REMS patents in Orange Book has direct effect on competition
 - 1. Brand firm gets automatic 30-month stay of FDA approval, no matter how weak the patent
 - 2. Generic firm cannot launch "at risk" (before court finds patent invalid or not infringed)
- B. 30-month stay and blocking of at-risk launch concerning given REMS patents' weaknesses
 - 1. *E.g.*: Entereg patent claims method for identifying hospital and registering hospital and patients in "computer readable storage media." U.S. Patent No. 8,645,160.
 - 2. *E.g.*: Xyrem patent claims "computerized method of distributing a prescription drug under exclusive control of an exclusive central pharmacy." U.S. Patent No. 7,668,730.
 - a. PTO invalidated all Xyrem patents through "inter partes" review¹
 - 3. Under landmark Federal Circuit decision, *Alice Corp. v. CLS Bank*, these are not patentable
 - a. *Alice* set forth 2-part test: (1) Are claims at issue directed to patent-ineligible concept? If so...(2) Does claim contain "inventive concept" sufficient to "transform" abstract idea into patent-eligible application? 573 U.S. 208, 217-18 (2014).
 - b. REMS patents cover abstract ideas and are put into effect only by using generic computer functions
- C. REMS patents particularly subject to harms; generics cannot pursue usual methods of avoiding patent by:
 - 1. seeking approval for alternative use other than use listed in patent (since REMS patents relate not to use of drug but to distribution method)
 - 2. claiming that its product would not infringe (since FDA requires the programs to be the same)

III. REMS Patents Undermine Statute

- A. Congress made clear in Food and Drug Administration Amendments Act of 2007 (FDAAA) that REMS patents should not be used to "block or delay" a generic application. 21 U.S.C. § 355-1(f)(8).
 - 1. Congress also provided that REMS programs would not burden the healthcare system, particularly for patients who "have difficulty accessing health care (such as patients in rural or medically underserved areas)" or those with "serious or life-threatening diseases or conditions." 21 U.S.C. § 355-1(f)(2)(C).
- B. REMS patents have in fact been used to block or delay generic competition and to burden the healthcare system
 - 1. 43 REMS patents cover Entereg, Pomalyst, Revlimid, Thalomid, and Xyrem.²
 - 2. *E.g.*: Jazz sued Roxane for infringement of REMS patents related to Xyrem.³

IV. Proposal

- A. The following amendment (with additions and ~~deletions~~) could be incorporated into the final sentence of 21 C.F.R. § 314.53(b)(1):

Process patents, patents claiming packaging, patents claiming metabolites, ~~and~~ patents claiming intermediaries, and patents claiming FDA-approved Risk Evaluation and Mitigation Strategies (REMS) required under 21 U.S.C. § 355-1(a)(1) are not covered by this section, and information on these patents must not be submitted to FDA.

¹ Matthew Bultman, *PTAB Nixes 6 Jazz Pharma Patents in AIA Review by Rivals*, LAW360 (July 28, 2016), <https://www.law360.com/articles/822645/ptab-nixes-6-jazz-pharma-patents-in-aia-reviews-by-rivals>.

² Michael A. Carrier & Brenna Sooy, *Five Solutions to the REMS Patent Problem*, 97 B.U. L. REV. 1661, 1673-74 (2017).

³ Carrier & Sooy, at 1681.